



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

8 APR 2016

MEMORANDUM FOR SGOZ

ATTN: CAPT BRYANT J WEBBER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **The Impact of Chagas Disease on Military Training in Texas** presented at **Military Health System Research Symposium Website** with MDWI 41-108, and has been assigned local file #**16134**.
2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH		2. FROM: (Author's Name, Rank, Grade, Office Symbol) Bryant J. Webber, Capt, USAF, MC, 559 THLS/SGOZ		3. GME/GHSE STUDENT: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		4. PROTOCOL NUMBER: 20140074H	
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.) The Impact of Chagas Disease on Military Training in Texas							
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: Prevalence and Seroprevalence of Trypanosoma cruzi among U.S. Military Members in South Texas							
7. FUNDING RECEIVED FOR THIS STUDY? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO FUNDING SOURCE: AFMSA							
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO							
9. IS THIS MATERIAL CLASSIFIED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO							
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.							
11. MATERIAL IS FOR: <input checked="" type="checkbox"/> DOMESTIC RELEASE <input type="checkbox"/> FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.							
<input type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.)							
<input checked="" type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.) Military Health System Research Symposium Website							
<input type="checkbox"/> 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)							
<input type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.)							
<input type="checkbox"/> 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)							
12. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).							
DATE March 31, 2016							
13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Webber, Bryant J. (bryant.webber@us.af.mil)						14. DUTY PHONE/PAGER NUMBER 671-4087	
15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.							
LAST NAME, FIRST NAME AND M.I.		GRADE/RANK		SQUADRON/GROUP/OFFICE SYMBOL		INSTITUTION (If not 59 MDW)	
a. Primary/Corresponding Author Webber, Bryant J.		O-3		559 THLS/ 559 MDG/ SGOZ			
b. Pawlak, Mary T.		O-3		559 THLS/ 559 MDG/ SGOZ			
c. Valtier, Sandra		GS-13		59 MDW/ ST/ CAMD			
d. Daniels, Candelaria C.		O-4				US Army Public Health Com	
e. Cropper, Thomas L.		GS-14		559 THLS/ 559 MDG/ SGOZ			
f. Tully, Charla C.		O-4				DIMO	
I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401 JP, AND 59 MDW 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.							
16. AUTHOR'S PRINTED NAME, RANK, GRADE Bryant Webber, Capt				17. AUTHOR'S SIGNATURE WEBBER.BRYANT.J.1270119383		18. DATE March 11, 2016	
19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Asha Mandhare, Major				20. APPROVING AUTHORITY'S SIGNATURE MANDHARE.ASHA.K.1120419753		21. DATE March 11, 2016	

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.		22. DATE RECEIVED 3/14/2016	23. ASSIGNED PROCESSING REQUEST FILE NUMBER 16134
24. DATE REVIEWED 15 Mar 2016		25. DATE FORWARDED TO 502 ISG/JAC	
26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES If yes, give date. <input type="checkbox"/> N/A			
27. COMMENTS <input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED The article is approved.			
28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Rocky Calcote, PhD, Clinical Research Administrator		29. REVIEWER SIGNATURE CALCOTE ROCKY D. 1178245844	30. DATE

2nd ENDORSEMENT (502 ISG/JAC Use Only)

31. DATE RECEIVED 14 March 2016		32. DATE FORWARDED TO 59 MDW/PA 17 March 2016	
33. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED Contains the appropriate disclaimer.			
34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Arlene R. Christilles, GS-14, Chief of Civil Law		35. REVIEWER SIGNATURE <i>Arlene R. Christilles</i>	36. DATE 3/17/16

3rd ENDORSEMENT (59 MDW/PA Use Only)

37. DATE RECEIVED 6 April 2016		38. DATE FORWARDED TO 59 MDW/SGVU 7 April 2016	
39. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED			
40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Christopher Carwile, TSgt/E-6, NCOIC, PA		41. REVIEWER SIGNATURE CARWILE CHRISTOPHER STEWART 1280477229 ON: 01/15/16 U.S. GOVERNMENT OUTDOOR OUTING BUT: USAF CIC: CARWILE CHRISTOPHER STEWART 1280477229 PUB: 2016-04-07 15:15:16 1280477229	42. DATE 7 April 2016

4th ENDORSEMENT (59 MDW/SGVU Use Only)

43. DATE RECEIVED		44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE	
45. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED			
46. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER		47. REVIEWER SIGNATURE	48. DATE

Prevalence and Seroprevalence of *Trypanosoma cruzi* among U.S. Military Members in South Texas

Bryant J. Webber, MD, MPH*; Mary T. Pawlak, MD, MPH*; Sandra Valtier, PhD*; Thomas L. Cropper, DVM, MPVM, DACVPM*; Sallie L. Hall*; Candelaria C. Daniels, PhD**; Charla C. Tully, DO***

*59th Medical Wing, Joint Base San Antonio – Lackland, Texas

**U.S. Army Public Health Command South, Joint Base San Antonio – Fort Sam Houston, Texas

***Defense Institute for Medical Operations, Joint Base San Antonio – Lackland, Texas

Background

An estimated 300 thousand U.S. residents are infected with *Trypanosoma cruzi*, the causative parasitic agent of Chagas disease. Although the majority of cases are in Latin American immigrants, evidence points to increasing incidence of autochthonous cases of Chagas disease. In its first year, this study reported the prevalence and seroprevalence of Chagas disease among military members who may be at increased risk due to field training activities conducted around the San Antonio area, where *T. cruzi*-infected triatomines have been identified.

Methods

U.S. Air Force basic training field instructors, students graduating from security forces training, and military working dog instructors volunteered to have blood drawn and answer a questionnaire regarding risk factors for Chagas disease. Real-time polymerase chain reaction (PCR) and two serologic tests (enzyme-linked immunosorbent assay (ELISA) for IgG and IgM and immunofluorescence assay (IFA) for IgG) were conducted on blood samples. Descriptive statistics were used to analyze the prevalence and seroprevalence of *T. cruzi* and risk factors.

Results

A total of 416 individuals were enrolled in 2015. Of the tests conducted (PCR [N=403]; ELISA [N=408]; IFA [N=408]), all were negative for *T. cruzi*. The participants reported a total of 3,038 (mean = 7) weeks spent in a triatomine-endemic field environment, 113,661 (mean = 273) weeks living or traveling in Southwest U.S. and Latin America, and 6,189 (mean = 15) weeks camping or hunting in Southwest U.S. and Latin America.

Conclusions

To date, this study demonstrates that Chagas disease is not a significant risk to military members conducting field training in south Texas. Study enrollment will continue with funding for 3,000 participants.

Disclosures

This project is funded by the Air Force Medical Support Agency (award # D-14-009). The views expressed are those of the authors and do not reflect the official views or policy of the Department of Defense or its Components. The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40.402.



59th Medical Wing (59th MDW)
Institutional Review Board (IRB)
59 Clinical Research Division/SGVUS
2200 Bergquist Dr, Bldg 4430, Lackland AFB, TX 78236-9908
Federal Wide Assurance #FWA00001750 and DoD Assurance #50007

NOTICE OF ACTION REGARDING IRB REVIEW

Date: 6 May 2015

TO: Capt Bryant Webber, SGOZ

Protocol Number: FWH20140074H (402055)

Title: The Impact of Chagas Disease on Military Training in Texas (#402055-1)

Your **Continuing Review 'Progress Report'** submitted on 10 Apr 2015 for the protocol named above was **Approved** by the convened IRB on **28 Apr 2015**. The Board determination is provided below:

Documents Reviewed: Progress Report, Literature Review, ICD stamped, Form A-1 Principal Investigator's Multi-Purpose Signature Sheet

IRB determinations:

The study risks continue to be minimized and reasonable in relation to the potential benefits, if any to subjects, and the importance of the knowledge that may reasonably be expected to result. Selection of subjects continues to be equitable. The plan continues to adequately monitor data for subject safety and to have adequate provisions for subject privacy and confidentiality. Informed consent will continue to be sought from each prospective subject and appropriately documented.

It was noted that the PI, 2 AIs, 1 RA, 3 RC's completed an approved investigator training program. No untrained investigator's were listed. The Board determined that only the investigator's listed below were approved for this study (all other previously listed investigators will be dropped from the study):

- Bryant Webber, PI (training expires 12/06/16)
- Dr. Sandra Valtier, AI (training expires 01/15/16)
- Capt Mary Pawlak, AI (training expires 08/18/17)
- David Hill, RA (training expires 09/30/17)
- Michele Tavish, RC (training expires 07/31/17)
- Lois Robinson, RC (training expires 10/10/17)
- Constance Kowat, RC (training expires 10/30/15)

The Board determined no changes were required for the study.

The Board determined external monitoring of the study was not necessary. The Board agreed that the Principal Investigator's designation of the **Medical Utilization** category of the Surgeon General's Community Health Project should remain unchanged.

The Board voted to **approve** this Progress Report as written and determined that it remains not readiness related. The **minimal risk** study was approved for one year. **The new expiration date is 27 May 2016** (based on this study's existing expiration date, which, the IRB will use as a fixed anniversary date, if IRB approval occurred within 30 days of expiration. The study will be reviewed in approximately **11 months** for continuing review. **The next progress report is due 12 Apr 2016** (See attached table). **FOLLOW-UP: CLOSED**

If you have requested funds, you should contact the CRD Resource Manager at (2-7924) as to the status of requested funds. **YOU ARE NOT AUTHORIZED TO USE YOUR SECTION'S O&M FUNDS.**

Name of Official
MARIA DOMINGUEZ

Title/Office Symbol/Phone
Protocol Assistant/SGVUS/2-7143/2-6095

Signature DOMINGUEZ.MARIA.E.
1231107742

Digitally signed by DOMINGUEZ.MARIA.E. 1231107742
DN: cn=US, o=U.S. Government, ou=DoD, ou=PKI,
ou=USAF, cn=DOMINGUEZ.MARIA.E.1231107742
Date: 2015.05.06 11:02:26 -0500

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DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

Deadline for New Protocol Submission (By 1600 hours, 4 th Monday previous month)	Progress Reports For studies expiring between		Progress Report And other reports Deadline	IRB MEETING	
	If your study expires	25 November – 25 December		to meet IRB on	24 Nov 15
26 Oct 2015	If your study expires	26 December – 26 January	turn in by	to meet IRB on	No Dec IRB
23 Nov 2015	If your study expires	27 January – 23 February	turn in by	to meet IRB on	26 Jan 16
25 Jan 2016	If your study expires	24 February – 22 March	turn in by	to meet IRB on	23 Feb 16
22 Feb 2016	If your study expires	23 March – 26 April	turn in by	to meet IRB on	22 Mar 16
28 Mar 2016	If your study expires	27 April – 24 May	turn in by	to meet IRB on	26 Apr 16
25 Apr 2016	If your study expires	25 May – 28 June	turn in by	to meet IRB on	24 May 16
23 May 2016	If your study expires	29 June – 26 July	turn in by	to meet IRB on	28 Jun 16
27 Jun 2016	If your study expires	27 July – 23 August	turn in by	to meet IRB on	26 Jul 16
25 Jul 2016	If your study expires	24 August – 27 September	turn in by	to meet IRB on	23 Aug 16
22 Aug 2016	If your study expires	28 September – 25 October	turn in by	to meet IRB on	27 Sep 16
26 Sep 2016	If your study expires	26 October – 22 November	turn in by	to meet IRB on	25 Oct 16
24 Oct 2016	If your study expires	23 November – 26 December	turn in by	to meet IRB on	22 Nov 16
	If your study expires	27 December – 24 January	turn in by	to meet Nov IRB	No Dec IRB

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